510(K) SUMMARY

SUBMITTER INFORMATION

A.	Company Name:	Pegasus Biologics, Inc.
B.	Company Address:	6 Jenner, Suite 150 Irvine, CA 92618
C.	Company Phone:	(949) 502-3240
D.	Company Facsimile:	(949) 502-3241
E.	Contact Person:	Pamela Misajon Vice President, RA/CA pmisajon@pegasusbio.com

SEP 21 2006

DEVICE IDENTIFICATION

A.	Device Trade Name:	DermADAPT™ Wound Dressing
B.	Common Name:	Dressing, Wound, Collagen
C.	Classification Name(s):	Unclassified
D.	Device Code:	KGN

IDENTIFICATION OF PREDICATE DEVICES

The DermADAPT™ Wound Dressing is substantially equivalent to many commercially available collagen-based wound dressings. Two specific predicate devices are BIOPAD® (Euroresearch S.R.L.) cleared under Premarket Notification Number K040283 and Stimulen™ Collagen (Southwest Technologies, Inc.) cleared under Premarket Notification Number K030774.

DEVICE DESCRIPTION

The Pegasus Biologics DermADAPT™ Wound Dressing is a decellularized, equine pericardial implant that has been crosslinked and passed USP Sterility testing. The product is non-pyrogenic and supplied for single use only. The product must be rinsed prior to use following the procedure described in the IFU.

INDICATIONS FOR USE

The Pegasus Biologics DermADAPT™ Wound Dressing is a collagen-based wound dressing for the local management of moderately to heavy exuding wounds, including:

- Partial and full thickness wounds,
- Draining wounds,
- Pressure sores/ulcers,
- Venous ulcers,
- Chronic vascular ulcers,
- Diabetic ulcers,
- Trauma wounds (e.g., abrasions, lacerations, partial thickness burns, skin tears),
- Surgical wounds (e.g., donor sites/grafts, post-laser surgery, post-Mohs' surgery, podiatric wounds, dehisced surgical incisions)

TECHNOLOGICAL CHARACTERISTICS

The components of the DermADAPT™ Wound Dressing are similar in basic materials, design, construction and performance to the predicate devices. The device consists primarily of Type 1 collagen that has been decellularized, crosslinked, and passes USP sterility testing, and is provided in dimensions appropriate for covering and protecting surface wounds.

BIOCOMPATIBILITY AND PERFORMANCE TESTING

Biocompatibility testing and *in vitro* bench testing has been conducted to evaluate the biological safety and biomechanical performance characteristics of the DermADAPT™ Wound Dressing. Biocompatibility test results indicate that the device satisfies all biocompatibility requirements. Biomechanical test results indicate that the dressing satisfies performance requirements for a wound dressing.

STERILITY

DermADAPT™ is subjected to 14 day USP sterility testing and USP endotoxin testing prior to release.

CONCLUSIONS DRAWN FROM STUDIES

The results of testing demonstrate that DermADAPT™ Wound Dressing is substantially equivalent to the predicate devices in design, function, source of substrate materials and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 21 2006

Pegasus Biologics, Inc.
% Ms. Pamela Misajon
Vice President, RA/CA
6 Jenner, Suite 150
Irvine, California 92618

Re: K061494
Trade/Device Name: DermADAPT™ Wound Dressing
Regulatory Class: Unclassified
Product Code: KGN
Dated: September 11, 2006
Received: September 13, 2006

Dear Ms. Misajon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K061494

Device Name: DermADAPT™ Wound Dressing

Indications for Use:

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Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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